K111462

SEP - 8 2011

Appendix 3: 510(k) Summary

As Required by 21 CFR 807.92

Submitter:	Anulex Technologies, Inc. 5600 Rowland Road, Suite 280 Minnetonka, MN 55343
Contact Person:	Rachel Kennedy Director, Regulatory Affairs and Quality Systems Anulex Technologies, Inc. Direct: 952.224.4034 Fax: 952.224.4040 E-Mail: rkennedy@anulex.com
Date Prepared:	May 25, 2011
Trade Name:	fiXate Tissue Band
Classification:	II
Product Code:	GZB 21 CFR 882.5880
Predicate Device(s):	The subject device is substantially equivalent to the following predicate devices: • Anulex Technologies Versaclose (K100572 cleared March 17, 2010) • Anulex Technologies Xclose™ Tissue Repair System (K091432 cleared June 12, 2009) • Advanced Neuromodulation Systems Swift-Lock Anchor (K092371 cleared December 23, 2009)
Device Description:	The fiXate Tissue Band consists of an adjustable loop of non-absorbable 2-0 suture with two (2) attached anchors. The construct is provided sterile and preloaded on a disposable delivery instrument. The instrument's needle facilitates placement of the suture by positioning the T-anchors in the sub-layer of tissue.
Indications for Use:	The fiXate Tissue Band is intended to be an accessory to the leads component of Spinal Cord Stimulator systems functioning to secure the lead to the fascia or inter-spinous/supra-spinous ligament.
Functional and Safety Testing:	Biocompatibility and bench testing were completed and support the safety and effectiveness of the fiXate Tissue Band.

Conclusion:	The fiXate Tissue Band is similar in intended use, materials, design, and performance characteristics to the Versaclose and Xclose Plus Tissue Repair Systems (K100572 and K091432) and has the same intended use as Advanced Neuromodulation Systems Swift-Lock Anchor (K092371). Substantial equivalence is demonstrated through the detailed device description, performance testing and conformance with voluntary performance standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Heath Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Anulex Technologies, Inc.
c/o Ms. Rachel Kennedy
Director of Regulatory Affairs & Quality Systems
5600 Rowland Road, Suite 280
Minnetonka, Minnesota 55343

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Re: K111462
Trade/Device Name: fiXate Tissue Band
Regulation Number: 21 CFR 882.5880
Regulation Name: Implanted Spinal Cord Stimulator for Pain Relief
Regulatory Class: Class II
Product Codes: GZB and GAT
Dated: August 2, 2011
Received: August 3, 2011

Dear Ms. Kennedy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K111462

Indications for Use Form

Device Name: fiXate Tissue Band

Indications for Use:

The FiXate Tissue Band is intended to be an accessory to the leads component of Spinal Cord Stimulator systems functioning to secure the lead to the fascia or inter-spinous/supra-spinous ligament.

Prescription Use ____X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

KRISTEN BOWSHER

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K111462